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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,763	12/22/2000	Kenneth Jacobs	GIN-6046CP	7028

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/745,763	JACOBS ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *265 and 267* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *265 and 267* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 265 and 267 are pending.

Applicants' amendment filed February 6, 2006 is acknowledged. Applicants' response has been fully considered. Claim 265 has been amended, and claim 266 has been cancelled. Therefore, claims 265 and 267 are examined.

Application Data Sheet

2. A supplemental application data sheet (ADS) containing the mailing address of Vikki Spaulding filed February 6, 2006 is acknowledged.

Withdrawn Claim Rejections - 35 USC § 101

3. The previous rejection of claim 266 under 35 U.S.C. 101, regarding utility, is withdrawn in view of applicants' cancellation of the claim in the amendment filed February 6, 2006.

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claim 266 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' cancellation of the claim in the amendment filed February 6, 2006.

5. The previous rejection of claim 265 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 4 in the amendment filed February 6, 2006.

Withdrawn Claim Rejections - 35 USC § 102

6. The previous rejection of claims 265 and 266 under 35 U.S.C. 102(a) as being anticipated by Jacobs *et al.* (WO 97/39030), is withdrawn in view of applicants' cancellation of the claim,

applicants' amendment to the claim, and applicants' response at page 5 in the amendment filed February 6, 2006.

7. The previous rejection of claim 265 under 35 U.S.C. 102(b) as being anticipated by Meng *et al.* (U.S. Patent 5,470,719), is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 5 in the amendment filed February 6, 2006.

Maintained Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 265 and 267 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The claims are directed to a polynucleotide comprising the sequence of SEQ ID NO:35, a specific fragment of SEQ ID NO:35, and a polynucleotide encoding a protein comprising the sequence of SEQ ID NO:36 (claim 265); and a gene corresponding to the cDNA sequence of SEQ ID NO:35 (claim 267). The specification indicates that the invention is related to the novel polynucleotides and the proteins encoded by such polynucleotides (page 5, lines 5-7), and a polynucleotide has been identified as clone "bu45_2", which encodes a secreted or transmembrane protein, and the nucleotide sequence of bu45_2 is determined as SEQ ID NO:35 (page 113, lines 2-15). The specification also indicates the nucleotide sequence of bu45_2 was searched against nucleotide sequence databases, which demonstrated at least some similarity with sequences identified as AA041196, AA452391, Q61260, R13864 and R18560; the predicted amino acid sequence for bu45_2 was searched against amino acid databases, which demonstrated at least some similarity to sequences identified as R99416 (aminopeptidase

precursor of Aeromonas caviae); and based on sequence similarity, bu45_2 proteins and each similar peptide may share at least some activity (page 113, lines 18-32). However, the specification does not disclose the sequence similarity between the identified polynucleotide sequences and SEQ ID NO:35, nor indicates the sequence similarity between the identified polypeptide sequences and bu45_2 proteins. Furthermore, the specification has not identified the activity of bu45_2 protein. Although the specification indicates the polynucleotides and the proteins of the invention such as SEQ ID NO:35 and SEQ ID NO:36 are expected to exhibit one or more uses or biological activities, such as polynucleotides can be used as markers for diagnosis, particularly, the polynucleotides of the present invention can be used as markers for tissues in which the corresponding protein is preferentially expressed (either constitutively or at a particular stage of tissue differentiation or development or in disease states) and for selecting and making oligomers for attachment to a gene chip (page 173, lines 21 to 29), and proteins may exhibit cytokine, cell proliferation activity, immune stimulating or suppressing activity (pages 173-189), the specification has not identified any tissue containing the expressed bu45_2 protein, nor has demonstrated the direct correlation between the expression of the bu45_2 protein in the tissues and the disease states. For these reasons, the instant invention does not possess a specific and substantial utility or a well-established utility for the claimed polynucleotides, although there is a general utility that is applicable to the broad class of proteins or polynucleotides. The utility is not a substantial utility because it requires further research to identify or reasonably confirm a "real world" context of use. Basic research to characterize the claimed invention, use in an assay to identify modulators of the instant invention, production of antibodies to identify other related

proteins or use of polynucleotides to identify other related sequences do not constitute substantial utilities.

Response to Arguments

Applicants indicate that the specification describes that the polynucleotides of the present invention can be used as markers for diagnosis. In particular, the polynucleotides of the present invention can be used as markers for tissues in which the corresponding protein is preferentially expressed (either constitutively or at a particular stage of tissue differentiation or development or in disease states), and for selecting and making oligomers for attachment to a "gene chip" (see page 173, lines 21 to 29), one skilled in the art would easily understand how to use the bu45 2 polynucleotide (SEQ ID NO: 35) as a marker for diagnosis. It has been held that a post-filing reference can be used to prove that the disclosure was in fact enabling as filed (See In re Brana, 51 F.3d 1560, 1567, n.19, 34 U.S.P.Q.2d 1436, 1444 n.19 (Fed. Cir. 1995). The asserted utility as a marker for disease diagnosis is substantiated by the document Cancer Research, vol. 63, February 2003, pp. 859-864, which indicates PGCP can be used as a marker for hepatitis C virus-associated hepatocellular carcinoma, and the bu45 2 polynucleotide is known as plasma glutamate carboxypeptidase (PGCP; see attached NCBI printout). In view of the foregoing, the present invention is supported by a specific and substantial asserted utility and/or a well-established utility (pages 4-5 of the response).

The response has been considered, however, the argument is not found persuasive because of the following reasons. Both the document in Cancer Research and the NCBI printout are post filing references, and the specification fails to identify the polynucleotide of SEQ ID NO:35 and the peptide of SEQ ID NO:36 as the nucleotide and polypeptide of plasma glutamate

carboxypeptidase (PGCP) at the time of filing of the instant application. Even if a post-filing reference can be used to prove that the disclosure was in fact enabling, the specification has not identified any tissue containing the expressed bu45_2 protein, nor has described the direct correlation between the expression of the bu45_2 protein in the tissues and the disease states, thus one skilled in the art would not know how to use the bu45 2 polynucleotide (SEQ ID NO: 35) as a marker for diagnosis. Therefore, the instant invention does not possess a specific and substantial utility or a well-established utility for the claimed polynucleotides.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 265 and 267 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

10. Claim 267 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 267 is directed to an isolated gene corresponding to the cDNA sequence of SEQ ID NO:35. While the specification indicates a gene corresponding to the cDNA sequence of SEQ ID NO:35 (page 19, lines 9 and 10), the specification does not specifically describes the

elements contained in the gene, e.g., the regulatory elements and untranslated regions, which are essential to the function of the claimed gene. Furthermore, SEQ ID NO:35 is essential to the function of the claimed gene, and the structure of the gene with naturally occurring regulatory elements and untranslated regions is empirically determined, and these elements are not conventional in the art (see Example 6 in Revised Interim Written Description Guidelines Training Materials). The lack of description for the structure of an isolated gene corresponding to the cDNA sequence of SEQ ID NO:35 as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 267 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 267 is indefinite because of the use of the term "corresponding to". The term cited renders the claim indefinite, it is not clear what is the relation between the gene and the cDNA sequence of SEQ ID NO:35, and whether the gene comprises the cDNA sequence of SEQ ID NO:35.

Conclusion

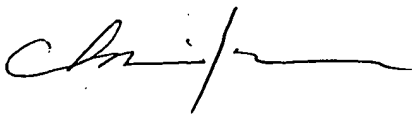
12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



CHIH-MIN KAM
PATENT EXAMINER

CMK
April 19, 2006